

## **REMARKS**

### **Request for Interview**

Applicant requests a telephone interview with the Examiner to discuss the scope of the pending claims and the disclosure of the document cited in the Office Action. Please contact Applicant's representative, Bill Isaacs, prior to further examination of this application.

### **Claims**

Claims 1-9, 12, 22-24, and 55-83 are pending in the application, with claims 1, 55, and 59 being independent. Claims 1, 55, and 59 have been amended herein. Claims 82-83 have been added to provide an additional scope of protection commensurate with the original disclosure. Claims 10-11, 13-21, and 25-54 were canceled previously.

Unless explicitly stated otherwise, none of the amendments to the claims were made for reasons substantially related to the statutory requirements for patentability. Furthermore, unless stated otherwise, the amendments to the claims were made simply to make express what had been implicit in the claims as originally worded and therefore are not narrowing amendments that would create any type of prosecution history estoppel.

### **Allowable Subject Matter**

In the Office Action, the Examiner objected to claims 77, 79, and 81 as depending from a rejected base claim and stated that those claims would be allowable if rewritten in independent form to include the features of the corresponding base claim and intervening claims from which they rely. Applicant has not rewritten claims 77, 79, and 81 in independent form because Applicant submits that the corresponding underlying base claims are patentable, as discussed in detail below.

### **Claim Rejections - 35 U.S.C. § 102(e)**

In the Office Action, the Examiner rejected claims 1-5, 8, 12, 22-24, 55-61, 76, 78, and 80 as allegedly being anticipated by U.S. Patent No. 6,532,386 to Sun et al. (hereinafter "Sun et al."). The Examiner also rejected claims 1-4, 6, 7, 22, 23, 55-57, 59, 60, 62-69, 76, 78, and 80 as allegedly being anticipated by U.S. Publication No. 2004/0049150 to Dalton et al. (hereinafter

“Dalton et al.”). Applicant respectfully traverses the rejection of these claims for the reasons discussed below.

*A. Sun et al.*

Sun et al. discloses a device comprising a plurality of blades in communication with a reservoir and an electrode, wherein the blades are used to transport a compound through a mammalian barrier membrane. Sun et al. further discloses, in one particular embodiment, that the blades may be made of a first material and *coated* with a second material. See Sun et al. at 7:10-14. Sun et al. consistently discloses a two-part device, with a first part serving as the blade and a fully discrete second part serving as a coating. See, e.g., Sun et al. at 7:22-26; 7:35-36; 8:1-2. Sun et al. does not disclose a microneedle made of a first material and a second material wherein the second material is dispersed throughout at least a portion of the first material, as similarly recited in independent claims 1, 55, and 59. In contrast, Sun et al. discloses a two-phase blade system, see Sun et al. at Fig. 1, wherein the first phase is a blade 106, and the second phase is a coating 107. Accordingly, Applicant submits that independent claims 1, 55, and 59, as well as all claims depending therefrom, are patentable over Sun et al.

*B. Dalton et al.*

Applicant first contends that Dalton et al. does not qualify as a proper 35 U.S.C. 102(e) reference because the present Application is entitled to the priority date of U.S. Provisional Patent Application No. 60/255,603 (“the Priority Application”), filed on Dec. 14, 2000. The earliest 102(e) date that Dalton et al. may claim is Jul. 18, 2001—the filing date of the international application. Because this date is later than the filing date of the Priority Application, Dalton et al. does not qualify as a 102(e) reference.

The Priority Application is a properly enabling reference, as shown in Applicant’s October 5, 2009 response to a previous non-final office action. Claims 1, 55, and 59 all recite that the second material comprises rigid particles that are dispersed throughout at least a portion of the first material. The Priority Application discloses, by way of example, the following: “In the third function, the additive remains, typically to serve a structural function (i.e. to lend mechanical strength or rigidity to the microneedles). For example, a dispersion of rigid salt particles in PLGA can enhance the rigidity of PLGA microneedles.” See Priority Application p.

16, lines 21-29. Accordingly, Applicant submits that the present Application is entitled to the Dec. 14, 2000 filing date of the Priority Application, thereby removing Dalton as a prior art reference.

Applicant also contends that even if Dalton et al. were a proper 102(c) reference, which it is not, it does not disclose the invention claimed in the Application. Dalton et al. discloses a reservoir and skin piercing protrusions used to deliver certain pharmaceutical agents into the skin of the human body. Dalton et al. further discloses that in certain embodiments the skin piercing protrusions may be *coated* with a reservoir medium. See Dalton et al. at ¶ 0015. Dalton et al. does not disclose a microneedle made of a first material and a second material, wherein the second material comprises rigid particles that are dispersed throughout at least a portion of the first material, as similarly recited in independent claims 1, 55, and 59. Accordingly, Applicant submits that independent claims 1, 55, and 59, as well as all claims depending therefrom, are patentable over Dalton et al.

#### **Claim Rejections - 35 U.S.C. § 103**

In the Office Action, the Examiner rejected claim 9 as allegedly being unpatentable over Sun et al. in view of Dalton et al. Applicant respectfully traverses the rejection of claim 9 because neither Sun et al. nor Dalton et al. disclose a microneedle made of a first material and a second material, wherein the second material comprises rigid particles that are dispersed throughout at least a portion of the first material, as recited by claim 9, as discussed above. Applicant further traverses the rejection because Dalton et al. does not qualify as prior art, as discussed above.

#### **Summary**

Applicant submits that independent claims 1, 55, and 59 are patentable over the documents cited in the Office Action. Additionally, the remaining claims depend from one of the independent claims either directly or indirectly and are submitted to be patentable for similar reasons. The dependent claims also recite additional features further defining the present invention over the cited documents, and Applicant submits that the cited documents do not teach or suggest integrating those features into the presently claimed invention. Accordingly, Applicant requests separate and individual consideration of each dependent claim.

**No Waiver**

All of Applicant's arguments and amendments are without prejudice or disclaimer. Applicant has not addressed each specific rejection of the independent and dependent claims because Applicant submits that the independent claims are allowable over the cited documents, as discussed above. Applicant has not acquiesced to any such rejection and reserves the right to address the patentability of any additional claim features in the future.

**CONCLUSION**

The foregoing is submitted as a full and complete response to the Office Action. If any issues exist that can be resolved with an Examiner's Amendment or a telephone conference, please contact Applicant's representative at the number provided below.

Respectfully submitted,

/William O. Isaacs, II/

William O. Isaacs, II  
Reg. No. 44,165

KING & SPALDING LLP  
1180 Peachtree Street, N.E.  
Atlanta, Georgia 30309-3521  
Telephone (404) 572-4600  
Facsimile (404) 572-5134